

METHOD OF PRODUCING SUBMICRON PARTICLES OF A LABILE AGENT
AND USE THEREOF

ABSTRACT

The present invention relates to a sustained release composition comprising
5 micron particles of labile agent and a method of preparing and using the sustained
release composition. The invention further relates to micron particles of a labile agent
and a method of preparing the micron particles.

The method of the invention for preparing a composition for the sustained
release of a labile agent, comprises forming a suspension comprising the labile agent
10 dispersed in a polymer solution comprising at least one biocompatible polymer and at
least one polymer solvent. The suspension is then wet milled to achieve micron
particles of the labile agent. The polymer solvent is then removed resulting in a solid
polymer/labile agent matrix. The composition for sustained release of a labile agent is
likewise prepared according to the method of the invention.

15 The sustained release composition of the present invention can be used in a
method for providing a therapeutically effective blood level of a labile agent, in a
subject in need of treatment with said agent, for a sustained period comprising
administering to the subject the sustained release composition described herein.

The method for preparing micron particles of a labile agent comprises forming a
20 suspension comprising the labile agent, dispersed in a polymer solution comprising at
least one biocompatible polymer and at least one polymer solvent, and wet milling of
the suspension. The submicron particles of labile agent, as described herein, are
prepared according to this method.